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## Skin regeneration and wound healing with a topical BRAF inhibitor

### Grant Award Details

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Skin regeneration and wound healing with a topical BRAF inhibitor

**Grant Type:** Late Stage Preclinical Projects

**Grant Number:** CLIN1-12946

**Project Objective:** The objective of this project is to complete manufacturing of LUT017 (small molecule) active pharmaceutical ingredient (API) and the final formulated drug product (DP); complete DMPK studies using the API, toxicology and efficacy studies using the DP; and complete an IND submission for testing this drug product in a clinical trial for patients with venous leg ulcers.

**Investigator:**

<b>Name:</b>	Antoni Ribas
<b>Institution:</b>	University of California, Los Angeles
<b>Type:</b>	PI

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**Disease Focus:** Skin Disease, Wounds, ulcers

**Award Value:** \$5,005,126

**Status:** Pre-Active

### Grant Application Details

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**Application Title:** Skin regeneration and wound healing with a topical BRAF inhibitor

**Public Abstract:**      **Therapeutic Candidate or Device**

LUT017 gel is a small molecule inhibitor of BRAF

**Indication**

Venus leg non-healing ulcerous wounds

**Therapeutic Mechanism**

The administration LUT017 gel will regenerate cutaneous stem cells and induce keratinocyte proliferation resulting in an improvement of VLU non-healing wounds.

**Unmet Medical Need**

There are no previously approved FDA drugs for this condition that affects to 1 out of 100 Californians.

**Project Objective**

Complete the IND-enabling studies

**Major Proposed Activities**

- Manufacture study drug, LUT017, Active Pharmaceutical Ingredient and the Formulated Drug Product (TU017 gel) to supply the proposed studies
- Evaluate study drug stability, efficacy and tolerability in different preclinical models
- IND submission and UCLA phase I clinical trial start-up submission

**Statement of Benefit to California:**

Non-healing skin ulcers affect 1 in 100 Californians, and there is currently no FDA-approved drug treatment. Topical use of a BRAF inhibitor regenerates skin stem cells in preclinical models, accelerating the wounds closure. Proposed studies will lead to an IND filing to test the safety and potential benefit of LUT017 for the treatment of chronic non-healing skin ulcers. Clinical success would result in the development of the first drug therapy for the treatment of non-healing cutaneous wounds.

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